REMARKS

Introduction

Claims 57-62, 64-73, 75, 77-88, 90, and 91 are pending in the application and are presented for the Examiner's review and consideration. Claim 66 has been amended; claim 89 has been canceled; and claims 90 and 91 have been added. Applicants believe that the claim amendment, cancellation, additions, and the accompanying remarks serve to clarify the present invention and are independent of patentability. Accordingly, Applicants respectfully submit that that they do not limit the range of any permissible equivalents.

As an initial matter, Applicants acknowledge the withdrawal of claim 82. Upon the allowance of a generic or linking claim, consideration of this claim is solicited. Applicants also note that claim 89 was rejected under the first and second paragraphs of 35 U.S.C. § 112. Although Applicants disagree with this rejection, claim 89 has been canceled to expedite allowance of this case, or, alternatively, to simplify the issue on Appeal.

Claims 66, 70, 80, 83-85, and 87-89 were rejected under 35 U.S.C. § 102(e) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,183,443 to Kratoska *et al.* ("Kratoska"). Claims 81 and 86 were rejected under 35 U.S.C. § 103(a) as unpatentable over Kratoska. Claims 66, 70, 71, and 83-85 were rejected under 35 U.S.C. § 102(b) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,312,417 to Wilk ("Wilk"). For the reasons set forth below, Applicants respectfully submit that the rejected claims are not taught or suggested by Kratoska or Wilk.

Rejections Based On Kratoska

As previously set forth in responses to prior Office Actions, Kratoska discloses an expandable introducer sheath. An expandable introducer sheath 200 includes an elongated flexible shaft 206 extending between distal end 202 and proximal end 204. (Column 24, lines 3-6). At least one rib 207 extends longitudinally on an inner wall of the sheath shaft 206. (Column 24, lines

9-10, and FIGS. 7A-7C). The rib abuts an outer wall of the intravascular device 214 thereby providing extra spacing between an inner wall of the sheath shaft 206 and an outer wall of the intravascular device 214. (Column 24, lines 51-54). This spacing or opening permits blood pressure monitoring, blood removal, blood delivery, or drug infusion through the sheath via the hub 208. (Column 24, lines 54-56). Kratoska discloses that several ribs may extend longitudinally along an inner wall of the sheath shaft 206. (Column 24, lines 56-61).

The Examiner states that "Kratoska et al., in figures 7A-7C, show tubular sheath 200 and an array of filaments 207 (as described in Col. 24, lines 57-61) which extend along an inner side of the passage of the sheath 200. . . . The array of filaments 207 blocks contact between an object inserted in the passage and the sheath (col. 24, lines 57-61)."

In contrast and as disclosed in the specification, a cannula 10 according to one embodiment of the present invention includes an expanding portion 12 with a plurality of filaments or wires 16 that are surrounded by an overlying elastic sheath 18. Specification, p. 7, lns. 15-20. The wires 16 engage the circumferential inner surface 56 of the sheath. *Id.*, p. 10, lns. 8-9.

> Thus, it is seen that the wires 16 have outer surface portions 60 disposed radially inwardly in the cannula 10 and forming contact surfaces for surgical instruments and the like inserted through the central instrument passage 20 of the cannula. The sheath 18 has an outer circumferential surface 54 engaging tissue when the cannula 10 is in use. The wires 16 block engagement of instruments inserted through the central instrument passage 20 of the cannula 16 with the elastic sheath 18. The sheath 18 blocks engagement of tissue with the wires 16, and the sheath and the wires block engagement of tissue with any instruments inserted through the cannula 10. *Id.*, p. 13, lns. 3-13.

Applicants submit that Kratoska does not disclose each and every element as set forth in claim 66, either expressly or inherently. For example, Kratoska does not disclose that the rib inhibits or blocks contact between an object inserted in the passage and the sheath. The Kratoska rib is disclosed as only forming a space between an inner wall of the sheath shaft and an outer wall of the intravascular device for the monitoring blood pressure and/or the insertion or removal of fluid from the body of the patient. As such, Kratoska does not expressly disclose that the

rib blocks contact between the inner surface of the sheath and the outer surface of the intravascular device.

Applicants further submit that it would not be inherent that rib blocks contact between the inner surface of the sheath and the outer surface of the intravascular device. Kratoska discloses that "[t]he sheath 200 should be lubricously coated (by silicone or hydrophilic lubrication) on its inner surface and outer surface to permit smooth movement of any intravascular device relative to the sheath. . . . In addition, a longitudinal stiffening member such as an elongate wire may be embedded in a wall of the sheath 200 or within a rib on the inner wall of the sheath 200. The stiffening member would provide additional support to prevent potential elongation of the sheath 200 when attempting to push a guide catheter (or other intravascular device) through the sheath 200. The potential for elongation of the sheath 200 occurs because of the friction caused between the outer surface of the guide catheter and the inner surface of the sheath 200 when the guide catheter is pushed through the sheath 200." (Column 25, lines 45-66.)

Accordingly, Kratoska expressly discloses that the inner surface of the sheath and the outer surface of the guide catheter will be in contact and provides specific methods for decreasing the friction and preventing elongation of the sheath caused by such contact. As such, Kratoska teaches away from the rib blocking contact between the inner surface of the sheath and the outer surface of the guide catheter. Accordingly, Applicants submit that Kratoska does not inherently disclose that the rib blocks contact between the inner surface of the sheath and the outer surface of the intravascular device.

The Examiner attempts to discount this specific teaching in Kratoska by asserting that:

> [a]lthough Kratoska et al. refers to friction caused between the outer surface of a guide catheter and the inner surface of the sheath 200 (col. 25, lines 65-67), it is clear that the inner surface referred to is on portion 207 of sheath 200 rather than the circular inner surface of shaft 206 in view of the additional spacing between the outer wall of the intravascular device and the inner wall of sheath shaft 206 described in col. 24, lines 57-61.

Applicants disagree. The only clear disclosure in Kratoska relates to the single rib

embodiment. To be sure, the use of several ribs is mentioned in passing, but there is nothing in Kratoska that teaches or suggests blocking or inhibiting contact with the sheath, regardless of the number of ribs used. Fig. 7C, the only clear drawing in Kratoska, shows significant contact between the inner surface of sheath 200 and the outer surface of intravascular device 214.

In order to clarify the present invention, claim 66 now recites that "the array of filaments blocks contact between an object inserted in the passage and said sheath maintaining the object in a spaced apart, non-contacting relationship with the sheath." Support for this amendment can be found in the specification at, for example, page 23 lines 24-26. As set forth in the specification, there is no contact between the sheath and an object inserted in the passage. *See, e.g.* Specification, page 8 lines 9-13 ("If not enough wires 16 are used, an instrument (trocar, insert, scope, etc.) inserted through the passage 20 when the cannula 10 is expanded will contact the elastic sheath 18 rather than the wires 16, at locations between the wires.").

In light of the foregoing, amended independent claim 66 is respectfully submitted to be patentable over Kratoska. As claims 70, 80, 83-85, 87, and 88 depend from claim 66 and necessarily include all the elements of their base claim, Applicants respectfully submit that these dependent claims are also allowable over Kratoska at least for the same reasons. Applicants also respectfully submit that the obviousness rejection of claims 81 and 86 need not be separately addressed since Kratoska does not teach or suggest all the elements of independent claim 66.

Rejections Based On Wilk

As previously noted, the Examiner also rejected independent claims 66 as anticipated by, or in the alternative, as obvious over Wilk.

Wilk discloses a laparoscopic cannula or trocar sleeve for use in laparoscopic surgery. (Column 3, lines 32-34). The cannula comprises a rigid tubular member 12 with an insufflation portion component 14 at a proximal end and an expandable receiver portion 16 at a distal end. (Column 3, lines 34-36). Receiver portion 16 includes an elastic or pleated web 18 provided along with an inner surface with a plurality of longitudinal extending resilient ribs 20. (Column

3, lines 39-42). Ribs 20 have an internal spring bias tending to maintain the ribs in a straightened configuration (FIG. 1). (Column 3, lines 42-44).

Upon pulling of a severed organ or organ part into the distal end of receiver portion 16, ribs 20 expand outwardly, thereby permitting a surgeon to pull the severed organ into the web 18. (Column 3, lines 44-47). Upon drawing of the severed organ into receiver portion 16, the entire cannula is withdrawn from the abdominal wall of the patient. (Column 2, lines 52-54). Receiver portion 16 expands from a substantially cylindrical insertion configuration shown in FIG. 1 to an expanded cup shaped pocket shown in FIG. 2. (Column 3, lines 36-39.)

The expandable receiver portion of the Wilk cannula has two components, a web provided along with a plurality of longitudinal extending resilient ribs. In use ribs expand outward, forming the receiver portion into a cup shape, allowing the surgeon to draw the severed organ into the web. The web supports the severed organ for removal from the patient abdomen. As such, Wilk discloses that the severed organ, the object inserted into the passage, is in contact with the web, *i.e.* the sheath.

In contrast, as noted above, claim 66 recites, *inter alia*, a sheath having an array of filaments on an inner surface that "blocks contact between an object inserted in the passage and said sheath maintaining the object in a spaced apart, non-contacting relationship with the sheath." As used in the specification, the blocking effect of the array of filaments prevents contact between the inserted object and the sheath. Wilk discloses that the severed organ is drawn into the web, wherein the web supports the severed organ for removal from the patient's abdomen. As such, Wilk does not expressly disclose that the ribs block contact between the inner surface of the web and the outer surface of the severed organ.

Applicants further submit that it would not be inherent that the ribs block contact between the inner surface of the web and the outer surface of the severed. Wilk discloses that the "ribs 20 may alternatively be attached to the outer surface of web 18." (Column 3, lines 56-57.) In such a configuration it would be impossible for the ribs to block contact to the inner surface of the sheath.

Additionally, the Wilk device is intended to remove a severed organ from the abdomen of a

patient. The severed organ has a conformal non-uniform cross section. Thus, it is inherent the severed organ will conform to the inner surface of the receiving member, conforming over the ribs to contact the web.

Furthermore, the web is made of an elastic material and the ribs are resilient. It is therefore inherent that the inner surface of the receiving portion, the web and the ribs, will conform around the severed organ to grip the organ for removal. Accordingly, Applicants submit that Wilk does not inherently disclose that the ribs block contact between the inner surface of the web and the outer surface of the severed organ.

In fact, the sole purpose for Wilk is to remove the organ through the cannula. Thus, Wilk would want the organ to adhere to the inner surface of the web. Additionally, Wilk would want to maximize the contacting surface area between the web and the organ.

In light of the foregoing, amended independent claim 66 is respectfully submitted to be patentable over Wilk. As claims 70, 71, and 83-85 depend from amended claim 66 and necessarily include all the elements of their base claim, Applicants respectfully submit that these dependent claims are also allowable over Wilk at least for the same reasons.

Conclusion

Claims 67-69 were objected to as being dependent upon a rejected base claim. As claims 67-69 depend from claim 66, which is believed to be allowable, Applicants hereby respectfully request reconsideration and withdrawal of the objection.

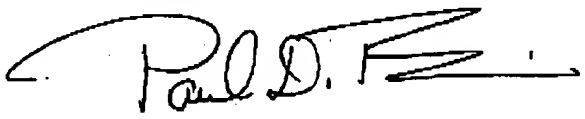
Finally, Applicants acknowledge with appreciation the continued allowance of claims 57-62, 64, 65, 72, 73, 75, and 77-79.

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

No fee is believed to be due for this submission. However, please charge the required fee

(or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket no. 780-A02-003-2).

Respectfully submitted,



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